

## **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

### **I. Claim Amendments**

Claims 1, 3-16 and 19 were pending in this application when examined.

Claim 14 is amended to become an independent composition (product) claim, and thus is not a “product-by-process” claim. The term “copolymer” replaces “resin composition”, and can be found in the marked-up version of the substitute specification filed February 10, 2006 (hereinafter referred to as “the specification”), for example, at page 4, line 3, page 8, line 18, page 9, line 18, page 10, line 8 and page 11, line 25.

Moreover, Applicants note that the specification states on page 15, lines 20-23 that “In addition, the weight ratio of polyvinyl alcohol, methyl methacrylate and acrylic acid upon copolymerization is the same as the weight ratio of polyvinyl alcohol, methyl methacrylate and acrylic acid in the copolymer, and is 60-90:7-38:0.5-12.”

Claim 14 is also amended to change “a polyvinyl alcohol” to “a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500”. Support for this amendment can be found on page 12, line 25 in the specification.

Support for “wherein said polymerizable vinyl monomer consists of acrylic acid and methyl methacrylate combined in the weight ratio of 3:7 to 0.5:9.5 in the copolymer” in amended claim 14 can be found on page 15, lines 10-12 in the specification.

Support for “a suitable carrier” in amended claim 14 can be found in the examples in the specification.

Claim 12 is amended to depend from claim 14, and to correspond with the amendments to claim 14.

Claim 15 is amended to correspond with the amendments to claim 14.

Claim 16 is amended to recite “A binder for a medicine, an animal drug, an agricultural chemical, a fertilizer or a food...”, comprising the components of claim 14. Support for the amendments to claim 16 can be found on page 9, line 24 – page 10, line 13 of the specification.

Claims 1-11, 13 and 19 are cancelled, and claims 21-27 are added.

Support for new claim 21 can be found on page 3, line 27 of the specification.

Support for new claim 22 can be found on page 12, lines 25-26 of the specification.

Support for new claims 23-27 can be found in Examples 2-5 and 7 of the specification.

## **II. Telephonic Interview With Examiner**

Applicants' thank the Examiner for the courtesies she extended to Applicants' representative during the telephonic interview held June 25, 2009. During the interview, the Examiner indicated that the information in the boxes in the right margin on pages 2-3 of the Office Action were inadvertently included in the Office Action, and that they should be ignored.

## **III. Claim Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Examiner maintains the rejection of claims 11 and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claim 11 is cancelled, rendering its rejection moot.

Claim 12 is amended to depend from claim 14. Claim 14 recites "a partially hydrolyzed polyvinyl alcohol". Accordingly, there is sufficient antecedent basis in claim 12 for "the partially hydrolyzed polyvinyl alcohol". Thus, reconsideration and withdrawal of the rejection are respectfully requested.

## **IV. The Characteristics of the Claimed Invention**

The composition of claim 14 is characterized by a combination of:

(1) a composition for coating medicines, animal drugs, agricultural chemicals, fertilizers or foods, and

(2) a copolymer of

(2-1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500;

(2-2) a polymerizable vinyl monomer

(2-3) in a weight ratio of 6:4 to 9:1 (i.e., 1.5 to 9:1); and

(2-4) the polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate combined in the weight ratio of 3:7 to 0.5:9.5 (i.e., 1:2.33 to 19).

Claim 16 is directed to (1') a binder for a medicine, an animal drug, an agricultural chemical, a fertilizer or a food, comprising (2) a copolymer having features (2-1),(2-2), (2-3) and (2-4), discussed above, and a suitable carrier.

**V. Claim Rejections Under 35 U.S.C. § 102**

**A. Hoshi et al.**

The Examiner rejects claims 1, 3-15 and 19 under 35 U.S.C. § 102(a) as being anticipated by Hoshi et al. (U.S. 2003/0166763). As applied to the amended claims, Applicants respectfully traverse the rejection.

Hoshi et al. describe a **hard capsule** that is made mainly of a polymer or a copolymer. Although the Examiner on page 5, 3rd paragraph states that "Regarding claim 13-15, Hoshi et al. discloses a coating agent comprising a resin composition for medicines, animal drugs or food ([0045-0048]), the reference does not disclose "A composition for coating medicines, animal drugs, agricultural chemicals, fertilizers or foods". Rather, the reference discloses a hard capsule, which can be filled with a medicine (see paragraph [0047]).

On the other, the claimed invention is directed to a **composition for coating** medicines, animal drugs, agricultural chemicals, fertilizers or foods, and **the process of coating** medicines, animal drugs, agricultural chemicals, fertilizers or foods. Hoshi et al. do not teach a composition for coating, and do not teach a process of coating.

Further, claim 14 recites "a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500".

Hoshi et al. describe in Synthesis Example 4 a copolymer consisting of (1) the mixture of **(i) a partially hydrolyzed polyvinyl alcohol (PVA) having a degree of polymerization 500 and (ii) a PVA having degree of polymerization 1700**, with (2) acrylic acid and methyl methacrylate (see paragraph [0059] and Table 4). Accordingly, Hoshi et al. do not teach a PVA having "an average polymerization degree of 300 to 500", but rather a **mixture** of two PVAs having an average polymerization degree of **500 and 700**.

On the other hand, in claim 14, the copolymer has (1) a polyvinyl alcohol **having an average polymerization degree of 300 to 500**, and (2) acrylic acid and methyl methacrylate. Thus, the copolymer of the present invention is different from that of Hoshi et al.

Moreover, in Synthesis Examples 1-3 of the reference, PVA-SH is used to prepare the copolymer, and PVA-SH is structurally different from the PVA-OH that is used in the present invention.

Accordingly, claim Hoshi et al. does not anticipate claim 14.

In addition, Applicants wish to point out that the composition for coating in the present invention would not have been obvious in view of a hard capsule that is made mainly of a polymer or copolymer, which is described in the Hoshi et al. reference.

Moreover, Applicants note that Hoshi et al. do not teach or suggest a process of coating medicines, animal drugs, agricultural chemicals, fertilizers or foods, as recited in claim 23, and a process of coating tablets of medicines, animal drugs, agricultural chemicals, fertilizers or foods, as recited in claim 26.

Therefore, claim 14 is clearly patentable over the cited reference.

Claims 12 and 15, and new claims 21-26, depend directly or indirectly from claim 14, and thus are also clearly patentable over the cited reference.

**B. Hoshi et al. in view of Saliba et al.**

The Examiner rejects claim 16 under 35 U.S.C. § 102(a) as being anticipated by Hoshi et al. as applied to claim 1, and in further view of evidence of Saliba et al. (U.S. 2003/0059649). As applied to the amended claims, Applicants respectfully traverse the rejection.

The Examiner states “Regarding claim 16, Hoshi et al. discloses a binder comprising a resin composition wherein a polyvinyl copolymers are binders in coating compositions as evidenced by Saliba et al. [0043]” (see Office Action, page 5, last paragraph).

Paragraph [0043] of the Saliba et al. reference states “Any binder customarily employed in coatings for magnetic tape can be used. For example...polyvinyl alcohol copolymers” (see lines 1-7). Thus, Saliba et al. do not teach the specific combination of a binder for a medicine, an animal drug, an agricultural chemical, a fertilizer or a food, comprising a copolymer of (2-1) a **partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500; (2-2) a polymerizable vinyl monomer, (2-3) in a weight ratio of 6:4 to 9:1; and (2-4) the polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate combined in the weight ratio of 3:7 to 0.5:9.5**, as recited in claim 16.

Rather, Saliba et al. merely discloses “polyvinyl alcohol copolymers”.

Accordingly, claim 16 is not anticipated by Hoshi et al., as evidenced by Saliba et al.

In addition, Applicants note that the composition for coating, and the process of coating, in the present invention would not have been obvious to a person skilled in the art, even if the hard capsule disclosed in Hoshi et al., which is made mainly of a polymer or copolymer, were combined with the mention of polyvinyl alcohol copolymers of Saliba et al.

Accordingly, the claimed invention is clearly patentable over Hoshi et al. and Saliba et al.

**C. Saiden Chemical**

The Examiner rejects claims 1 and 3-14 under 35 U.S.C. § 102(b) as being anticipated by Saiden Chemical Industry Co., Ltd (JP 2002-105383) ("Saiden Chemical"). As applied to the amended claims, Applicants respectfully traverse the rejection.

As discussed above, claim 14 recite (1) a composition for coating medicines, animal drugs, agricultural chemicals, fertilizers or foods, comprising (2) a copolymer of **(2-1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500; (2-2) a polymerizable vinyl monomer, (2-3) in a weight ratio of 6:4 to 9:1; and (2-4) the polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate combined in the weight ratio of 3:7 to 0.5:9.5.**

Saiden Chemical describes a water-based gas-barrier coating composition comprising (A) 100 parts by weight of a copolymer composition containing mainly methacrylic alkyl ester, and (B) 40-200 parts by weight of polyvinyl alcohol with a saponification (i.e., hydrolyzation) degree of not less than 93 mol.%.

The reference specifically describes in Examples 1-3, a coating agent containing (1) a copolymer of (i) a polyvinyl alcohol (PVA) series resin of polymerization degree of 1,700 with (ii) an ester of acrylic (or metacrylic) acid, and (2) a PVA series resin of polymerization degree of 500. Further, the reference specifically describes in Examples 4-5, a coating agent containing a copolymer of (1) a mixture of (i) a PVA series resin of polymerization degree of 1,700, and (ii) a PVA series resin of polymerization degree of 500 with (2) an ester of acrylic (or metacrylic) acid.

However, the reference does not teach the specific combination of features (1), (2), (2-1), (2-2), (2-3) and (2-4), as recited in claim 14.

Accordingly, claim 14 is not anticipated by the reference.

Claim 12 depends from claim 14, and thus also is not anticipated by the reference.

In addition, Applicants note that the reference teaches in paragraph [0018] that “The degree of saponification of the amount of the polyvinyl alcohol system resin used beyond 93 mole% used for this invention is a 40-200 weight part to a copolymer constituent 100 weight part. When there is less amount used than 40 weight parts, workability is good, but gas barrier nature runs shot. When exceeding 200 weight parts, the constituent of high concentration hypoviscosity is not obtained. It is a 60-150 weight part preferably”.

Thus, the reference teaches that a polyvinyl alcohol is used in an amount of 40-200 weight parts relative to 100 weight parts of the copolymer, preferably 60-150 weight parts, and **teaches that if more than 200 weight parts of the polyvinyl alcohol are used, then the desired product in the reference cannot be obtained.**

On the other hand, in the claimed invention, a copolymer of a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500 and a polymerizable vinyl monomer is used in a **weight ratio of 6:4 to 9:1 (i.e., 1.5 to 9:1)**. In other words, in the claimed invention, there are **150-900 weight parts of polyvinyl alcohol relative to 100 weight parts of a polymerizable vinyl monomer**. Therefore, reference clearly teaches away from the recited range of a weight ratio of 6:4 to 9:1 (i.e., 150-900 weight parts of PVA to 100 weight parts of polymerizable vinyl monomer), as recited in claim 14.

Further, the viscosity of the copolymer in Example 1 of the present invention is 104 mPa · s/25°C, but the viscosity of the copolymer of working Examples in Sainen Chemical is 530 to 2600 mPa · s/30°C, as shown in the table below:

<u>Example</u>	<u>Viscosity (mPa · s/30°C)</u>
1	530
2	1,000
3	620
4	840
5	2,600

Accordingly, it would not have been obvious to coat tablets or granules with the composition disclosed in the reference, because the viscosity of the copolymer is very high, and the tablets or granules would adhere to each other. Further, it would not have been obvious to carry out spray-coating, as recited in claims 24-25, because of the high viscosity of copolymer.

Furthermore, problems to be solve in the present application (i.e., the shrinkage of a film which is seen at lack of an adhesion force to an uncoated tablet surface, and unclearness of an embossed mark accompanied with floating, "bridging phenomenon"), as described on page 18, lines 24-27 of the specification, is not described in Saiden Chemical, and would not have been obvious from the disclosure of the reference. Thus, the effect of not creating a bridging phenomenon is not described or suggested in the reference.

Accordingly, claim 14 is clearly patentable over the reference.

Claim 12 depends from claim 14, and thus also is clearly patentable over the reference.

**D. Saiden Chemical in view of Saliba et al.**

The Examiner rejects claim 16 under 35 U.S.C. § 102(b) as being anticipated by Saiden Chemical, and further in view of evidence of Saliba et al. As applied to the amended claims, Applicants respectfully traverse the rejection.

As discussed above, Saiden Chemical describes a coating agent. However, the reference does not teach the specific combination of (1') a binder for a medicine, animal drug, an agricultural chemical, a fertilizer or a food, comprising (2) a copolymer of **(2-1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500; (2-2) a polymerizable vinyl monomer, (2-3) in a weight ratio of 6:4 to 9:1; and (2-4) the polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate combined in the weight ratio of 3:7 to 0.5:9.5**, as recited in claim 16.

Moreover, as discussed above, Saliba et al. merely mention on lines 1- 7 of [0043] that "Any binder customarily employed in coatings for magnetic tape can be used. For example,...polyvinyl alcohol copolymers".

Therefore, Saiden Chemical in combination with Saliba et al. do not teach the specific combination of features (1') (2), (2-1), (2-2), (2-3) and (2-4), as recited in claim 16. Accordingly, claim 16 is not anticipated by the reference.

Moreover, the references do not suggest the specific combination of features (1') (2), (2-1), (2-2), (2-3) and (2-4), as recited in claim 16, and thus one of ordinary skill in the art would not have arrived at the binder of claim 16 from the disclosures of the references.

Accordingly, claim 16 is clearly patentable over the references.

## **VI. Claim Rejections Under 35 U.S.C. § 103**

The Examiner rejects claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Saiden Chemical, as applied to claim 1, in view of Keith et al. (U.S. Patent No. 4,432,965); rejects claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Saiden Chemical; and rejects claims 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Saiden Chemical, as applied to claims 17 and 18, and further in view of Keith et al. As applied to the amended claims, Applicants respectfully traverse the rejections.

As discussed above, Saiden Chemical describes a coating agent. However, the reference does not teach the specific combination of (1) a composition for coating medicines, animal drugs, agricultural chemicals, fertilizers or foods, comprising (2) a copolymer of **(2-1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500; (2-2) a polymerizable vinyl monomer, (2-3) in a weight ratio of 6:4 to 9:1; and (2-4) the polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate combined in the weight ratio of 3:7 to 0.5:9.5**, as recited in claim 14.

Keith et al. describe a sustained release polymeric coating, which contains from about 5-20 wt% of polyethylene glycol component and from about 80-95 wt% of a polyvinylalcohol component (see claim 1 of the reference).

However, Keith et al. do not teach or suggest the specific combination of (2) a copolymer having features (2-1), (2-2), (2-3) and (2-4), as recited in claim 14.

Therefore, claim 14 would not have been obvious over Saiden Chemical in view of Keith et al.

Claim 15 depends from claim 14, and thus also would not have been obvious over the references.

Claims 17-20 are cancelled, rendering their rejection moot.

## **VII. New Claims**

New claims 21-27 depend directly or indirectly from claims 14 and 16, and are thus distinguished over the cited references for at least the reasons discussed above with respect to claims 14 and 16. Accordingly, prompt examination and allowance of claims 21-27 are respectfully requested.



**VIII. Information Disclosure Statement**

Applicants respectfully request the Examiner to consider the references cited in the Information Disclosure Statement filed December 3, 2009.

**IX. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance.

Should the Examiner find that anything further would be desirable in order to place the application in better condition for allowance, she is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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December 14, 2009